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Tadayo Hata

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

03/23/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Note:

The proposed amendment raises new issues that would require further consideration and/or search with respect to the addition of "freeze-dried bacterial cells or wet bacterial cells..." in claim 4 and the addition of "purified bacterial cells or freeze-dried bacterial cells ..." in claim 6 including new issues under 35 U.S.C § 112.

The rejection under 35 U.S.C 112, regarding deposit is withdrawn in view of applicant's averments.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

It should be kept in mind that applicant cannot, as a matter of right, amend any finally rejected claims, add new claims after a final rejection (see **37 CFR 1.116**) or reinstate previously canceled claims.

Except where an amendment merely cancels claims, adopts examiner suggestions, removes issues for appeal, or in some other way requires only a cursory review by the examiner, compliance with the requirement of a showing under **37 CFR 1.116(b)(3)** is expected in all amendments after final rejection, i.e., "An amendment touching the merits of the application or patent under reexamination may be admitted upon a showing of good and sufficient reasons why the amendment is necessary and was not earlier presented."

Applicant argues that whether the cells are "dead" or "live" is clarified by reciting "purified bacterial cells or freeze-dried bacterial cells". It is noted that the amendment to claim 4 recites "freeze-dried bacterial cells or wet bacterial cells". Moreover, applicant has not explained with any particularity the nexus between determination of whether cells are "dead" or "live" and the recitation of "purified bacterial cells or freeze-dried bacterial cells". Therefore, the rejection is deemed proper and it is maintained for the reasons of record.

Regarding claim 6, the relevance of the treatment of periodontal disease, chronic sinusitis, bronchitis and bed sores and the prevention or treatment of any and all infections in any

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and all animals, including humans, and any and all plants with an unknown amount of a strain and an unknown amount of an unknown antibiotic has not been delineated with any specificity.

With respect to the art rejections, there is no clear indication in the claim designated preparation that the particular strain is provided in an amount sufficient to discern functions and effects that would distinguish the claimed material over the reference material. No amount is stipulated. Therefore, these arguments fail to persuade.

Therefore the rejections are deemed proper and are adhered to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651